been subjected to restriction by the Examiner under 35 U.S.C. §121 (37 C.F.R. §1.142) as follows:

I. Claims 1-35, drawn to a delta 6-desaturase gene, plants transformed therewith, and a method of producing a transformed plant with increased GLA by transforming plants with said gene, classified in class 800, subclass 298;

II. Claims 36-37, drawn to a method of producing a transformed plant with increased GLA by transforming plants with a delta-6 desaturase gene and a delta-12 desaturase gene, classified in class 800, subclass 281;

III. Claims 38-46, drawn to a method of inducing production of octadecatetraeonic acid, classified in Class 800, subclass 278.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents three distinct inventions stating that:

> The inventions of Groups I-III are distinct methods and products given that each method requires different method steps and different components, and each results in the production and isolation of chemically and structurally distinct products. Thus, the inventions of Groups I-III are each capable of being separately made, independently used ... Office Action, page 2.

Accordingly, it is the Examiner's position that each group of claims set forth above requires individual consideration as to patentability.

As indicated, and in order to be fully responsive to the Examiner's requirement for restriction, Applicants provision-

ally elect to prosecute the subject matter of Group I, Claims 1-35 and reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof for the following reasons.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. 35 U.S.C. §121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without independence and distinctness, a restriction requirement is unauthorized.

It is respectfully submitted, that in the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. The claims of Group I, Claims 1-35, are drawn to a delta-6 desaturase gene, and plants transformed with such gene. A method of inducing or increasing production of gamma

linolenic acid (GLA) in an organism deficient, lacking in, or producing low levels of GLA by transforming said organism with a vector comprising the subject evening primrose delta-6 desaturase gene (Claim 35) has also been grouped in Group I. Claim 37, however, which has been placed in Group II by the Examiner, similarly recites a method of inducing production of gamma linolenic acid (GLA) in an organism deficient, lacking in, or producing low levels of GLA and linoleic acid (LA) which comprises transforming said organism with a vector comprising the subject evening primrose delta-6 desaturase and an isolated nucleic acid encoding a delta-12 desaturase. Claims 35 and 37 both require the same evening primrose delta-6 desaturase. Both claims recite a method of inducing production of gamma linolenic acid (GLA) in an organism deficient or lacing in or producing low levels of GLA. Claim 37 also recites that the organism is deficient or lacking in or produces low levels of linoleic acid (LA) and recites the additional step of transforming the organism with an isolated nucleic acid encoding a delta-12 desaturase. Claim 37 does not however, result in the production and isolation of chemically and structurally distinct products.

Claims 38-46 are directed to methods of inducing octadecatetraeonic acid in a plant deficient or lacking in or producing low levels of same or a bacterium which exhibits a delta-15 desaturase activity on a GLA substrate by transformation with the subject evening primrose delta 6-desaturase. As stated on page 13 of the subject specification, "[i]n the transgenic

organisms of the present invention, octadecatetraeonic acid results from further desaturation of α-linolenic acid by Δ6-desaturase or desaturation of GLA by Δ15-desaturase. The methods recited in Claims 36-37 do not require method steps or components different from that required in Claims 1-35. Thus, Claims 1-35, Claim 37, and Claims 38-46 are very clearly interrelated and interdependent, not "independent and distinct."

The interdependence of the recombinant delta 6-desaturase gene, plants transformed therewith, a method of producing a transformed plant with increased GLA by transforming plants with the delta 6-desaturase gene alone or a delta 6-desaturase gene and a delta 12-desaturase gene, and a method of inducing production of octadecatetraeonic acid in a plant by transforming with the subject delta 6-desaturase gene is confirmed --indeed, it is mandated-- by virtue of the fact that the description requirements of 35 U.S.C. §112 compel disclosure of all aspects of the invention in the one application which applicants have filed. An application claiming a method of inducing production of octadecatetraeonic acid in a plant deficient, lacking in, or producing low levels of octadecatetraeonic acid is required to disclose inter alia, how to make that invention: in other words, a description of the subject 6-desaturase gene is a mandatory part of the application. Likewise, an application claiming a DNA encoding a delta 6-desaturase, plants transformed therewith, and a method of producing a transformed plant with increased GLA, is required to

disclose inter alia how to make and use the delta 6-desaturase gene, such as in a method for producing a transformed plant with increased GLA by transforming plants with the delta 6-desaturase gene either alone, or along with the delta 12-desaturase gene, or in a method for production of octadecatetraeonic acid (Claims 38-46). Indeed, if any of these aspects of a complete disclosure were omitted --perhaps by an applicant relying on what the Patent and Trademark Office considers "independent and distinct"-- the application could be considered defective under §112, first paragraph.

Consequently, it is clear that aspects of a given invention, such as a product and various uses of the product, are necessarily interdependent, not independent, from each other.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one

aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), Applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or a compromise of the term of their patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit (CAFC) has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784

F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) the CAFC held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

The particular reason given by the Examiner to justify restriction between Groups I, II, and III is that the methods and products as claimed are capable of being separately made and independently used. The Examiner has then stated that since the "inventions" are distinct for this reason, they have acquired a

separate status in the art due to their divergent subject matter as shown by their separate classification.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

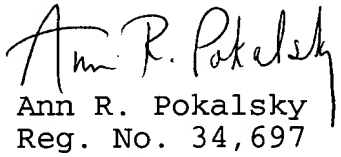
The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims he assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in

response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Hence, it is again respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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